

Attachment IV: Summary of Safety and Effectiveness Information

Synthes (USA)
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Synthes commercially available Drill Bits are being made available as sterile.

Synthes Sterile Drill Bits are intended to bore a hole into bone for insertion of a screw, wire, cable, plate, pin, bolt, etc.

Synthes Sterile Drill Bits are available in various sizes and lengths, have a fluted design, and are either solid or cannulated, and may be calibrated. The Synthes Sterile Drill Bits have various coupling mechanisms.

Synthes Drill Bits will be provided to the user sterile. Gamma radiation will be used to sterilize the device.